



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: James CUNNINGHAM et al.

Title: MILLING MICROGRAM QUANTITIES OF

NANOPARTICULATE CANDIDATE COMPOUNDS

Appl. No.: 10/736,989

Filing Date: 12/17/2003

Examiner: Unassigned

Art Unit: 3725

<u>INFORMATION DISCLOSURE STATEMENT</u> <u>UNDER 37 CFR §1.56</u>

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document, except as noted below, is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone:

(202) 672-5538

Facsimile:

(202) 672-5399

Michele M. Simkin

Attorney for Applicants

By Michel M Minha

Registration No. 34,717

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

an required to respond to a collection of information unless it contains a valid OMB control Under the Paperwork Reduction Act of 1995, no perse number.

Sheet

Substitute for form 1449B/P700	Co	omplete if Known
	Application Number	10/736,989
STATEMENT BY APPLICANTANT	Filing Date	12/17/2003
	First Named Inventor	James Cunningham
(use as many sheets as necessary TRADE	Group Art Unit	3725
(use as many sheets as necessary TRADE	Examiner Name	Unassigned
1 of 3	Attorney Docket Number	029318-0997

U.S. PATENT DOCUMENTS									
Examiner Initials*	Cite No. ¹	U.S. Patent D	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear			
	A1	4,848,676	1	STEHR	07/18/1989				
	A2	5,145,684		LIVERSIDGE ET AL.	09/08/1992				
•	A3	5,298,262		NA ET AL.	03/29/1994				
	A4	5,302,401		LIVERSIDGE ET AL.	04/12/1994				
	A5	5,318,767		LIVERSIDGE ET AL.	06/07/1994				
	A6	5,328,404		BACON	07/12/1994				
	A7	5,336,507		NA ET AL.	08/09/1994				
	A8	5,336,662		LEE	08/09/1994				
	A9	5,340,564		ILLIG ET AL.	08/23/1994	*			
	A10	5,346,702		NA ET AL.	09/13/1994				
	A11	5,349,957		YUDELSON	09/27/1994				
	A12	5,352,459		HOLLISTER ET AL.	10/04/1994				
	A13	5,399,363		LIVERSIDGE ET AL.	03/21/1995				
	A14	5,401,492		KELLAR ET AL.	03/28/1995				
	A15	5,429,824		JUNE	07/04/1995				
	A16	5,447,710		NA ET AL.	09/05/1995				
	A17	5,451,393		LIVERSIDGE ET AL.	09/19/1995				
	A18	5,466,440		RUDDY ET AL.	11/14/1995				
	A19	5,470,583		NA ET AL.	11/28/1995				
	A20	5,472,683		ILLIG	12/05/1995				
	A21	5,494,683	}	LIVERSIDGE ET AL.	02/27/1996				
	A22	5,500,204		OSIFO	03/19/1996				
	A23	5,506,192		ANDERSON ET AL.	04/09/1996				
	A24	5,518,187		BRUNO ET AL.	05/21/1996				
	A25	5,518,738	1	EICKHOFF ET AL.	05/21/1996				
	A26	5,521,218		OSIFO	05/28/1996				
	A27	5,525,328		BACON ET AL.	06/11/1996				
	A28	5,543,133		SWANSON ET AL.	08/06/1996				
	A29	5,552,160		LIVERSIDGE ET AL.	09/03/1996				
	A30	5,560,931		EICKHOFF ET AL.	10/01/1996				
	A31	5,565,188		WONG ET AL.	10/15/1996				
	A32	5,569,448		WONG ET AL.	10/29/1996				
	A33	5,571,536		EICKHOFF ET AL.	11/05/1996				
	A34	5,573,749		ILLIG	11/12/1996				
	A35	5,573,750		SINGH	11/12/1996				
	A36	5,573,783		DESIENO ET AL.	11/12/1996				
	A37	5,580,579		RUDDY ET AL.	12/03/1996				
	A38	5,585,108		RUDDY ET AL.	12/17/1996				
	A39	5,587,143		WONG	12/24/1996				
	A40	5,591,456		FRANSON ET AL.	01/07/1997				
	A41	5,593,097	Y-1	CORBIN	01/14/1997				

Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

¹ Unique citation designation number. 2See attached Kinds of U.S. Patent Documents. 3Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

Substitute for form 1449B/PZ PE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as neocessary)

Sheet 2 of 3 TRADELING

Complete if Known				
Application Number	10/736,989			
Filing Date	12/17/2003			
First Named Inventor	James Cunningham			
Group Art Unit	3725			
Examiner Name	Unassigned			
Attorney Docket Number	029318-0997			

	U.S. PATENT DOCUMENTS							
	U.S. Patent D	ocument						
A42	5,593,657		RUDDY ET AL.	01/14/1997				
. A43	5,608,101	Ì	LEE ET AL.	03/04/1997				
A44	5,622,938	1	WONG	04/22/1997				
A45	5,628,981		LIVERSIDGE ET AL.	05/13/1997				
A46	5,643,552		ILLIG	07/01/1997				
A47	5,718,388		CZEKAI ET AL.	02/17/1998				
A48	5,718,919		RUDDY ET AL.	02/17/1998				
A49	5,747,001		WIEDMANN ET AL.	05/05/1998				
A50	5,797,550		WOODALL ET AL.	08/25/1998				
A51	5,834,025		DE GARAVILLA ET AL.	11/10/1998				
A52	5,862,999		CZEKAI ET AL.	01/26/1999				
A53	6,045,829		LIVERSIDGE ET AL.	04/04/2000				
A54	6,068,858		LIVERSIDGE ET AL.	05/30/2000				
. A55	6,153,225		LEE ET AL.	11/28/2000				
A56	6,165,506		JAIN ET AL.	12/26/2000				
A57	6,221,400	B1	LIVERSIDGE ET AL.	04/24/2001				
A58	6,264,922	B1	WOOD ET AL.	07/24/2001				
A59	6,267,989	B1	LIVERSIDGE ET AL.	07/31/2001				
A60	6,270,806	B1	LIVERSIDGE ET AL.	08/07/2001				
A61	6,316,029	B1	JAIN ET AL.	11/13/2001				
A62	6,375,986	B1	RYDE ET AL.	04/23/2002				
A63	6,428,814	B1	BOSCH	08/06/2002				
A64	6,431,478	B1	REED ET AL.	08/13/2002				
A65	6,432,381	B1	LIVERSIDGE ET AL.	08/13/2002				
A66	6,555,139	B2	SHARMA	04/29/2003				
A67	6,582,285	B1	CZEKAI ET AL.	06/24/2003				
A68	6,592,903	B2	RYDE ET AL.	07/15/2003				
A69	2002/0012675	A1	JAIN ET AL.	01/31/2002				

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Office	oreign Patent D	Nocument Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	A70	EP	338 992	A2	SANDOZ AG	10/25/1989	<u> </u>	
	A71	EP	394 889	B1	SANDOZ AG	10/31/1990		
	A72	EP	506 967	B1	NEW OJI PAPER CO. LTD.	10/07/1992		
	A73	EP	137 963	B1	STAUFFER CHEMICAL COMPANY	04/24/1985		
	A74	EP	186 118	B1	STAUFFER CHEMICAL COMPANY	07/02/1986		

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control

number.

	Substitute for	r form 1449B	PT9	(IPE)		Complete if Known	
	INFORMATION	ON DISCLO	SPRE	7	Application Number	10/736,989	
	STATEMENT	T BY APPLI	CANT	IAY 2 5 2004 9	Filing Date	12/17/2003	
			1 4	MY 5 2 500	∦ irst Named Inventor	James Cunningham	
			12.	A	Group Art Unit	3725	
	(use as many s	heets as ne	ce s 😪	(X)	Examiner Name	Unassigned	
Sheet	3	of	3	TRADENTA	Attorney Docket Number	029318-0997	

FOREIGN PATENT DOCUMENTS

	T	F	oreign Patent D		OREIGN PATENT DOCUMEN	Date of Publication of Cited Document	Pages, Columns, Lines, Where	[
Examiner Initials*	Cite No. ¹	Office	e ³ Number ⁴	Kind Code ⁵	Name of Patentee or Applicant of Cited Documents	MM-DD-YYYY	Relevant Passages or Relevant Figures Appear	Т6
	A75	EP	186 119	B1	STAUFFER CHEMICAL COMPANY	07/02/1986		
•	A76	EP	186 120	B1	STAUFFER CHEMICAL COMPANY	07/02/1986		
	A77	ΕP	249 150	B1	STAUFFER CHEMICAL COMPANY	12/16/1987		
	A78	EP	336 898	A2	SANDOZ AG	10/11/1989		
	A79	EP	461 079	B1	NOVARTIS AG ET AL.	12/11/1991		
-	A80	EP	549 524	A1	SANDOZ-PATENT-GMBH	06/30/1993		
	A81	EP	315 589	B1	ILFORD LIMITED	09/08/1993		
•	A82	WO	91/10653	A1	E.I. DU PONT DE NEMOURS AND COMPANY	07/25/1991		
	A83	wo	02/098565	. A1	ELAN PHARMA INTERNATIONAL LIMITED	12/12/2002		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A84	BEVAN, "A high-throughput screening method for the determination of aqueous drug solubility using laser nephelometry in microtiter plates", <i>Anal. Chem.</i> , 72:1781-7, (Apr. 15, 2000).	
	A85	HERTZBERG, "High-throughput screening: new technology for the 21 st century", <i>Curr. Opin. Chem. Biol.</i> , 4:445-51, (2000).	
	A86	LEUNER ET AL., "Improving Drug Solubility for Oral Delivery Using Solid Dispersions", Eur. J. Pharm. Biopharm., 50:47-60 (2000).	
	A87	MCNAME, "Robotised assays", Lancet, 346:114 (1985).	
	A88	PANCHAGNULA ET AL., "Biopharmaceutics and pharmacokinetics in drug research", Int. J. Pharm., 201:131-50 (May 25, 2000)	

Examiner Signature	Date Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, PO Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, Virginia 22313-1450.

¹ Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.